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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|---------------------------|-------------|----------------------|--------------------------|-----------------|
| 10/629,200 | 07/29/2003 | Paul O. Sheppard | 00-32C1 | 5535 |
| 7590 02/08/2006 | | | EXAMINER | |
| Robyn Adams | | | RAO, MANJUNATH N | |
| Patent Departm | | | | |
| ZymoGenetics, Inc. | | | ART UNIT | PAPER NUMBER |
| 1201 Eastlake Avenue East | | | 1652 | |
| Seattle, WA 98102 | | | DATE MAIL ED: 02/08/2006 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | | |
|--|---|--|--|--|--|--|--|
| | 10/629,200 | SHEPPARD ET AL. | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | |
| | Manjunath N. Rao, Ph.D. | 1652 | | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the co | orrespondence address | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim ill apply and will expire SIX (6) MONTHS from to cause the application to become ABANDONED | l. ely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | | |
| Status | | | | | | | |
| 1) Responsive to communication(s) filed on 29 Ju | lv 2003. | | | | | | |
| <u> </u> | action is non-final. | | | | | | |
| · <u> </u> | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Disposition of Claims | | | | | | | |
| 4)⊠ Claim(s) <u>1-21</u> is/are pending in the application. | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | |
| 6) Claim(s) is/are rejected. | | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | | |
| 8) Claim(s) 1-21 are subject to restriction and/or e | election requirement. | | | | | | |
| Application Papers | | | | | | | |
| 9) The specification is objected to by the Examiner | r. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | |
| * See the attached detailed Office action for a list of | of the certified copies not received | d. | | | | | |
| Attachment(s) | | | | | | | |
| 1) Notice of References Cited (PTO-892) | 4) Interview Summary (| | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | Paper No(s)/Mail Da 5) Notice of Informal Pa | te atent Application (PTO-152) | | | | | |
| Paper No(s)/Mail Date | 6) 🔲 Other: | • | | | | | |

DETAILED ACTION

Claims 1-21 are presently pending in this application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 15, and 21, drawn to a polypeptide, classified in class 436, subclass86.
- II. Claims 5-14, drawn to polynucleotides, vectors, host cells and method of making the polypeptide, classified in class 435, subclass 69.1.
- III. Claims 16-18, drawn to an antibody and a method of producing an antibody, classified in class 530, subclass 387.1.
- IV. Claim 19-20, drawn to a method of detecting the presence of Zsig47 gene, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III are patentably distinct from each other. The polypeptide of group I, the polynucleotide of group II, and the antibody of group III, each comprise amino acid sequences and nucleotide sequences which are chemically unrelated, do not require each other for practice; have separate utilities, such as use of the group I polypeptide to make specific antibodies versus the use of polynucleotide in a hybridization reaction and are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

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Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides can be used to make recombinant protein as opposed to its use in the method of group IV.

Inventions I, III and IV are patentably distinct from each other. The polypeptide of group I and the antibody of group III is neither made nor used in the method of group IV. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder of restricted inventions

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to rejoin, in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the

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limitations of the product claims. **Failure to do so may result in a loss of rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Manjunath N. Rao, Ph.D.

Primary Examiner
Art Unit 1652

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January 31, 2006